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REGENERATION TECHNOLOGIES, INC. c/o MCANDREWS, HELD & MALLOY 500 WEST MADISON STREET 34TH FLOOR CHICAGO, IL 60661			PREBILIC, PAUL B	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/782,594

Filing Date: February 12, 2001

Appellant(s): BIANCHI ET AL.

Sarah A. Kofflin
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 30, 2008 appealing from the
Office action mailed April 4, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The pending appealed cases mentioned by the Appellant are the only ones that the Examiner is aware. That is, Application Serial Numbers 10/387,322 and 09/905,683.

(3) Status of Claims

The statement of the status of claims contained in the brief is not concise. A concise statement of the status of the claims is as follows:

This appeal involves claims 26 to 30.

Claims 1-25 and 31-62 have been canceled.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The Appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The arguments suggesting that the rejection is untenable are not appropriate for this section of the appeal brief.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

EP-0517030	SIEBELS et al	05-1992
US 5,898,289	COATES et al	11-1999

Merriam-Webster Online definition of the term "allograft" located at:
[www.m-w.com/cgi-bin/dictionary?book+=Dictionary &va=allograft](http://www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels et al (EP 0517030) in view of Coates et al (US 5,989,289). Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together to form an implant by aligning bores of adjacent pieces. Next, Siebels introduces pins into the aligned bones to hold the implant pieces together; see Figures 1 and 2 and page 8 of the translation, first full paragraph and page 9 of the translation. Siebels also discloses that "the hollow space is filled with bone material or bone cement for the purpose of a radial anchoring of the ring"; see page 5 of the translation. Also, on page 11 of the translation, Siebels discloses that "extraneous bone material, or the patient's

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own bone material" can be used to fill the cavity. However, Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6).

Coates, however, teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties *in vivo*; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61. Therefore, it is the Examiner's position that it would have been obvious to make the disks and pins of the Siebels implant out of cortical bone for the same reasons the Coates teaches doing the same.

Regarding claims 28-30, the spacers of Coates can have osteogenic material of demineralized bone and/or allograft bone applied to them such that the pin(s) of Siebels, which would be made into bone because of the teachings of Coates, would also have these materials applied to them. Any segment thereof could be said to be made of cortical bone. "Allograft" is a homograft (i.e. from the same species) that is allogenic (i.e. genetically distinct) to the recipient; see Merriam-Webster Online at www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft. Since the bone of Coates is capable of being used as a bone graft unit upon the death of the individual, it is considered an allograft bone portion with respect to another human being to the extent that this language can be given patentable weight. The site or source of the material is relative to how it can be used and is not indicative of the material itself because the bone implants of Coates are allogenic with respect to another human

being. For these reasons, the separated bone pieces are grafts and allografts when these terms are given their broadest reasonable interpretation. The claim language requiring "machined" bone portions is not structurally distinguishing from that disclosed by Coates because it does require any particular structure in the device; see MPEP 2113 that is incorporated herein by reference.

(10) Response to Argument

The Appellant argues that the prior art provides no basis to combine the reference teachings; see page 13 of the appeal brief. However, the Examiner has pointed out the basis for the combination in the second paragraph of the rejection as providing an implant material with "superior properties *in vivo*; see the abstract, column 2, lines 33 to column 3, line 45, column 7, lines 18-43 and column 11, lines 42-61" of Coates.

Next, the Appellant argues that the cited references, as a whole, would lead one away from the proposed combination; see page 15 of the appeal brief. However, the Examiner asserts that Siebels is referring more to the assembly and sizing of the device just prior to surgery rather than the overall process of making. Furthermore, if the prior art had difficulty in making bone grafts from the perspective of Coates, than Coates at least implicitly can be said to overcome such difficulties. For this reason, there would be nothing stopping an ordinary artisan from applying the teaching of Coates to that of Siebels to arrive at the claimed invention. Moreover, a preference for a certain material, as in Siebels, is not a teaching away from other materials; see MPEP 2123 (II) that is incorporated herein by reference thereto.

The Appellant also argues that Siebels only suggests making implants out of plastic even when it states “solid disks can be manufactured of any biologically compatible material.” This argument is not considered persuasive because the plain language of Siebels does not suggest such a limited understanding and because the use of plastics is considered to be mere exemplification or preference for making the device. Moreover, Coates provides the clear motivation to make the implant pieces of Siebels out of bone.

Moreover, the Appellant argues that Siebels is limited to easy manufacturing but then points out that this can include winding techniques, braiding machines, PTFE mandrels with polygonal grooves, etc.; see page 18 of the brief. This disclosure of Siebels appears to make the mere cutting and machining described by Coates to be drastically simpler and easier.

In response to the argument that Coates describes the difficulty in making grafts out of bone, the Examiner asserts that Coates is discussing the prior art techniques. Furthermore, if the prior art had difficulty in making bone grafts from the perspective of Coates, than Coates at least implicitly overcame such difficulties. One has to presume that US patents are operable until evidence is provided to the contrary; see MPEP 716.07 that is incorporated herein by reference.

Next, the Appellant argues that there is no reasonable expectation of success with respect to combining the prior art teachings. However, the Appellant appears to require absolute predictability. The Examiner asserts that the combination provides a

reasonable expectation of success even though it does not provide proof of success. A reasonable expectation of success is required, not actual evidence of success.

Finally, the Appellant argues that the combination does not teach all the claimed elements; see page 24 of the appeal brief. However, the Examiner notes that cortical bone is taught by Coates as the implant material. Furthermore, Siebels teaches that it was known to utilize bone material to fill the bone implant. For these reasons, the Examiner asserts that it would have been clearly obvious to make the disks and pins of Siebels out of cortical bone because Coates teaches making the entire implant out of cortical bone was known.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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